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EXAMINER

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ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 10/20/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.



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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Paper No. 25

Application Number: 09/526,547
Filing Date: March 16, 2000
Appellant(s): FEDIDA, JOSE

James E. Ledbetter
For Appellant

EXAMINER'S ANSWER

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This is in response to the appeal brief filed 7/22/2003.

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(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences, which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

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(7) Grouping of Claims

The appellant's statement in the brief that **each** of the claims does not stand or fall together is not agreed with because if one dependent claim, which includes all the limitations of an associated independent claim, falls then the associated independent claim must fall as well.

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

5,609,627	GOICOECHEA et al.	3/1997
5,873,906	LAU et al	2/1999

(10) Grounds of Rejection

The following ground(s) of rejection (which are substantially the same as the previous "Final Rejection/paper #18") are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application

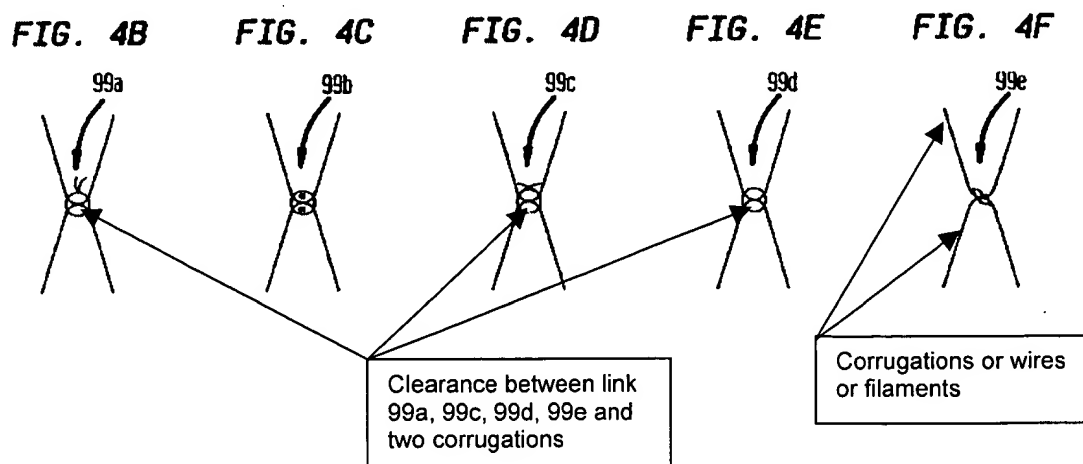
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by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

1. Claims 18-19, 22, 26-27, 29-30, 33, and 37-38 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over GOICOECHEA et al (5,609,627).

As to claims 18-19, 22, 26-27, 29-30, 33, and 37-38, GOICOECHEA (Figs. 1-7) discloses a prosthesis with graft/impervious envelope 62 and stent 52 (Fig. 5) to be implanted in a human passage as shown, for example, in Fig. 4A formed by zigzag-shaped nitinol wire/filament (column 8, lines 64-67) to define approximately annular units/corrugations linked together by links/loops 99c/rings 99d/staples 99e of nitinol wire (column 9, lines 58-61).

Further as to claim 18 and 29, GOICOECHEA (col. 9, lines 58-61; Fig. 4b-4f) discloses links 99a-99f formed of loops 99a, ring 99d or staples 99f as shown below:



GOICOECHEA, Fig. 4B-4F

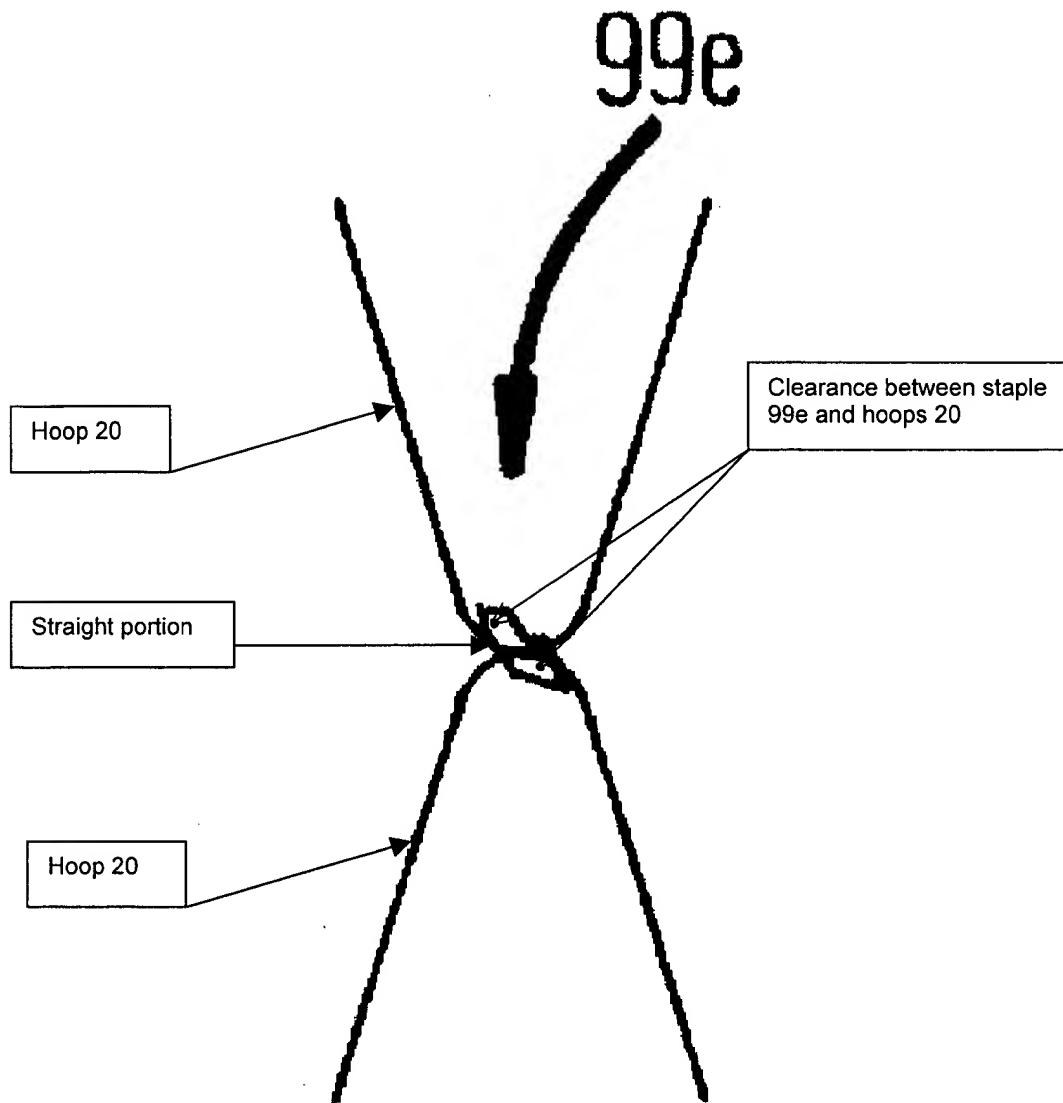


Fig. 4F (GOICOCHEA-'627)

Notice that Fig. 4B-4F all show some clearance between links 99a-99e and corrugations/wires/filaments, and as other links 99a-99d show only curved shapes of beads, rings or loops, Fig. 4F shows staple 99e having at least a straight segment in a

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central portion and some clearance between link 99e and the corrugations 20, which connection between staple 99e and the two corrugations 20 with some clearance is suitable for a flexibility of the GOICOCHEA stent. A provision of a clearance between a link 99e and two adjacent corrugations or wires or filaments for a stent flexibility is well-known in the art, it would not be necessarily for GOICOCHEA to explicitly describe the clearance in the specification, but this well-known inherent feature of GOICOCHEA stent would be well recognized by one of ordinary skill in the art.

In addition, as to claims 18 and 29, GOICOCHEA discloses staples 99e as links connecting two adjacent corrugations. **GOICOCHEA must inherently indicate 99e as conventional staple used with a conventional stapler because GOICOCHEA does not further describe or specify staple 99e in the specification. A conventional staple and stapler are well known, it is not necessary for GOICOCHEA to further describe or specify a conventional staple and stapler in his invention disclosure.**

Notice that a conventional U-shaped staple, for example a stapler and a staple in an office environment to hold objects/sheets of paper together, includes:

1. One single/sole straight central portion connecting two loops at both ends of the central portion in a linking position to hold the objects (objects here are sheets of paper, for example).

2. Each of two loops allows (a) a first shape of an arc of a circle prior to linking formed by two arc-shaped recesses in the anvil of a stapler when a U-shaped staple is pressed against the anvil (please see any paper stapler in an office) and (b) a second

3. In the linking position, two closed loops of the staple entrap the objects and link the two objects together.

Further, a conventional staple as discussed above is also well known to one of ordinary skill in the art and it would not be necessarily for GOICOECHÉA to fully describe a conventional staple link so as to define his invention.

Since the flexibility of a prosthesis device such as a stent or stent-graft is required to facilitate the deployment of the device along a tortuous blood vessel, staples 99e of nitinol wire as taught by GOICOECHÉA (Fig. 4F) must inherently entrap the zigzag-shaped wires/corrugations or filaments with some clearance (as shown in Fig. 4F). The clearance between staple 99e and the two adjacent corrugations or wires or filaments in GOICOECHÉA stent is well recognized by one of ordinary skill in the art and clearly shown in the Fig. 4F. Notice that partially closed or entirely closed loops of staples 99e would both function well for the GOICOECHÉA stent as long as the loops of staples 99e entrap the zigzag-shaped wires/corrugations with some clearance and the gap of the partial closed loop is smaller than a diameter of the wires or filaments or corrugations.

Alternatively, GOICOECHÉA discloses a conventional staple 99e connecting two adjacent corrugations with some clearance (clearly shown in Fig. 4F) between the staple 99e and the corrugations/wires/filaments for the flexibility of the stent. The

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connection between a conventional staple and two objects/wires is well known to have a central portion between two loops holding two objects such as two wires.

Because the connection is conventional and well known, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the staples 99e to entrap the zigzag-shaped wires/corrugations by partially closed or entirely closed loops of staples 99e with some clearance (for the stent flexibility) and with all other features as recited in the claims, as these configurations would provide linking means allowing a flexibility of the GOICOECHEA device for easy deployment in a tortuous blood vessel.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 23, 34 and 28, 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over GOICOECHEA et al (5,609,627).

As to claims 23, 34 and 28, 39, GOICOECHEA reference inherently discloses the claimed invention except for hexagonal opening mesh and a turned-back region at least at one of the ends of the stent. Hexagonal opening mesh is well known in stent art, and

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a stent-graft having a graft with a turned-back section at the end(s) of the stent-graft to form a tight seal between the graft and an inner vessel wall is well known in the art. It would have been obvious to one of ordinary skill in the art to modify GOICOECHEA stent-graft to have the features as claimed to provide a seal between the stent-graft and the inner wall of a vessel.

2. Claims 21, 24-25, 32, and 35-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over GOICOECHEA et al (5,609,627) as applied to claims 18 and 29 above, and further in view of LAU et al (5,873,906).

As to claims 21 and 32, GOICOECHEA reference inherently discloses the claimed invention except for the links/staples 99e with loops in two different planes. However, LAU (Fig. 2 or 9; column 14, lines 38-42) discloses links having loops in different planes to secure two adjacent annular units of a stent. It would have been obvious to one of ordinary skill in the art to make GOICOECHEA links/staples 99e with loops in different planes as recited in the claims, for this configuration would be another good way to secure two adjacent annular units of GOICOECHEA stent.

As to claims 24-25 and 35-36, GOICOECHEA reference inherently discloses the claimed invention except for the links/staples 99e are made of a radiopaque material such as gold, platinum, tantalum. However, LAU (Fig. 2 or 9; column 14, lines 38-42) discloses links made of a radio opaque material such as gold, platinum, tantalum to connect two adjacent annular units of zigzag-shaped wire. It would have been obvious to one of ordinary skill in the art to make links/staples 99e of a radiopaque material such

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as tungsten or platinum or tantalum or tungsten in view of LAU for the radiopaque material such as tungsten or platinum or tantalum would be proper for linking two adjacent annular units together.

Allowable Subject Matter

Claims 20 and 31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

(11) Response to Argument

Referring to section VIII of the "Appeal Brief" (paper #25), the response for the arguments is presented below:

A. Rejections of claims 29 and 40 as being indefinite because the recitation "said clearance" in the claims lack antecedent basis:

The appellant's amendment to replace "said clearance" with --a clearance—to overcome the rejection **has been entered to reduce or simplify the issues for appeal**. The argument is therefore moot in view of this "Examiner Answer".

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B. Rejection of claims 18, 19, 22, 26, 27, 29, 30, 33, 37 and 38 as being anticipated by GOCOICHEA:

The Appellant (page 16, lines 6-14) mainly argued that GOICOECHEA reference does not disclose:

1. Each of the links is provided with a sole central portion and two loops, one loop at each of the ends of the central portion.
2. Each of the two loops allows (a) a first shape of an arc of a circle prior to linking and (b) a second shape of an entirely closed loop, in the linking position.
3. Each of the two closed loops of each of the links entraps, in the linking position, with some clearance, a respective one of two of the corrugations, which are linked together.

In response, the Appellant is directed to 102(b) rejection of this office action, which provide a reasoning as to why the 102(b) rejection under inherency is proper and as to why missing descriptive matter is inherently present in the GOCOICHEA reference and that it would be well recognized by one of ordinary skill in the art.

Further, as pointed out by the Appellant, there is other designs of staples, such as a staple having U-shaped configuration in a linking condition used in a construction environment (lines 16-20, page 18, "Appeal Brief"). However, one of ordinary skill in the art would not consider the construction staples as suitable for connecting two adjacent corrugations in a stent, because the construction staples would be easily detached from the corrugations and cause danger to a patient. It is reasonable to consider the staple

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link in the GOICOCHEA reference as a conventional staple because GOICOCHEA does not disclose anything more specific about the staples.

GOICOCHEA does not need to disclose further detail about staples 99e because the staples in the reference are well known conventional staples.

In addition, from last two line of page 19 to line 12, page 20, section B, "Appeal Brief (paper 24)" of the Appellant, the Appellant argued that GOICOCHEA discloses two apices 22 of two neighboring hoops 20 are "juxtapose" and by definition from American Heritage College Dictionary, 4th edition, 2002, "juxtapose" means "side by side" or "next to each other" or "nearest in space or position" and therefore, the Appellant concluded that the two apices 22 are in contact to each other.

However, from American Heritage College Dictionary, 3rd edition, "side by side" also means "close together" (please see attached) and from Merriam-Webster's College Dictionary, 10th edition, 2000, "side by side" means "beside one another" (please see attached). Therefore, it would be clear that GOICOCHEA does not require two apices 22 of two neighboring hoops 20 being in contact to each other, but GOICOCHEA only requires two apices 22 of two neighboring hoops 20 disposed close together or beside one another.

C. Rejection of claims 18, 19, 22, 26, 27, 29, 30, 33, 37 and 38 as being unpatentable over GOICOCHEA:

The Appellant (from line 12 page 27 to line 17 page 28) mainly argued that GOICOCHEA staples are different from the links of the instant invention as below:

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1. GOICOCHEA staple 99e has only one loop and does not have a central portion.
2. GOICOCHEA staple 99e forming a loop entrapping two corrugations.
3. GOICOCHEA staples 99e have limited suppleness since the staples firmly grip the filament (of the corrugations).
4. Prior to linking, GOICOCHEA has a shape of a U.
5. GOICOCHEA staple 99e is liable to damage the filament or the corrugations.

In response, the Appellant is directed to the 103(a) rejection of this office action.

Further, as to Appellant arguments 1-3 and 5 above, from Figs. 4B, 4D, 4E, GOICOCHEA clearly shows circular loops or rings with some clearance between the loops/rings and the two corrugations. On the other hand, in Fig. 4F, GOICOCHEA clearly shows staple 99e having a straight central portion and some clearance between staple 99e and the two corrugations and therefore, staple 99e does not firmly grip the filament of the two corrugation to be liable to damage the filament of the corrugations as suggested by the Appellant and GOICOCHEA links 99e do provide plenty of suppleness for the stent. GOICOCHEA does not explicitly show two loops or describe two loops in staple 99e in a linking position because a conventional staple does have that feature and by indicating link 99e as a staple, GOICOCHEA clearly define his invention with no need to provide further explanation.

As to argument 4, two ends of GOICOCHEA U-shaped conventional staple (as recognized by the Appellant in line 12, page 28, "Appeal Brief") must have a shape of

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an arc prior to a linking position when staple 99e is pressed against two arc-shaped recesses formed in the anvil of stapler to link the two corrugations.

D. Rejection of claims 23, 28, 34 and 39 as being unpatentable over

GOICOCHEA:

The Appellant mainly contended that the rejection of independent claims 18 and 29 were not proper in view of GOICOCHEA reference.

In response, the Appellant is directed to the rejection and remarks presented earlier in this paper.

E. Rejection of claims 21, 24, 25, 32, 35 and 36 as being unpatentable over

GOICOCHEA:

The Appellant mainly contended that the rejection of independent claims 18 and 29 were not proper in view of GOICOCHEA reference.

In response, the Appellant is directed to the rejection and remarks presented earlier in this paper.

F. Objection to the drawings for failing to show the feature recited in lines 12-15 of claim 40:

New "Fig. 7, paper 20" and "amendment E, paper 19" filed after "Final Rejection, paper 18" **have been entered to reduce or simplify the issues for appeal.**

Claim 40 added in "amendment D, paper #17" after "First Rejection, paper #15" recites features that were not supported by a drawing or a complete description in the specification, therefore, it was not clear what was the invention at the time the "Final Rejection, paper 18" was issued and a thorough search and examination of claim 40 on the merits at that time was not possible.

Claim 40 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: as support for claim 40, "amendment E, paper #19" and new "Fig. 7, paper #20" were introduced after "Final Rejection, paper #18"; from amendment E and new Fig. 7, it is clear that claim 40 has been directed to an invention different and distinct from the invention originally claimed.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 40 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

G. Objections to claims 20 and 31 for depending from a rejected based claim:

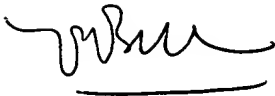
Claims 20 and 31 contain an allowable subject matter not disclosed or fairly suggested in the prior art of reference. Therefore, claims 20 and 31 are objected as dependent on a rejected base claims 18 and 29 respectively.

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Conclusion

According to the rejection above and the response to the Appellant's argument (from section A to section G), it is believed that the rejections should be sustained.

Respectfully submitted,



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October 16, 2003



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